UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/250,882	02/16/99	RUSSELL J	3131.US.02

023492
ABBOTT LABORATORIES
DEPT. 377 - AP6D-2
100 ABBOTT PARK ROAD
ABBOTT PARK IL 60064-6050

HM12/0725

EXAMINER	
MYERS, C	
ART UNIT	**PAPER NUMBER**
1655	18

DATE MAILED: 07/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action	Application No. 09/250,883	Applicant(s) RUSSELL ET AL.	
	Examiner Carla Myers	Art Unit 1655	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 July 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *10 July 2001*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search. (see NOTE below);

(b) ☐ they raise the issue of new matter. (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See attachment*.

4.☐ Applicant's reply has overcome the following rejection(s): _____.

5.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

6.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attachment*.

7 ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8.☐ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *9, 13-20 and 24*.

Claim(s) withdrawn from consideration: _____.

9. ☐ The proposed drawing correction filed on _____ a)☐has b)☐ has not been approved by the Examiner.

10.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

11.☐ Other:

ATTACHMENT TO ADVISORY:

1. The proposed amendments to the claims raise new issues that would require further search and consideration. In particular, the amendment to limit the claims to a "breast tissue-specific polynucleotide comprising" any one of SEQ ID NO: 1-14 raises new issues under 35 U.S.C. 112 first paragraph, with respect to written description and enablement. It is noted that the currently pending claims are limited to sequences which consist of SEQ ID NO: 1-14 or sequences which are 90% identical over the full length of the sequence to SEQ ID NO: 1-14. The currently pending claims do not require a polynucleotide comprising SEQ ID NO: 1-14 wherein the polynucleotide has the property of being breast tissue-specific. The proposed amended are inclusive of nucleic acids in which only a portion of the nucleic acid (SEQ ID NO: 1-14) is defined in terms of its structure. The nucleic acids may comprise any flanking sequences, and yet must also be breast tissue-specific. The sequences of SEQ ID NO: 1-13 consist of overlapping fragments of 83-293 bases in length. It is not clear as to whether these sequences constitute full exons or only partial exons. Accordingly, the proposed amended claims have been interpreted as encompassing genomic sequences, in which the intronic and surrounding exonic sequences have not been defined in terms of their chemical structure. For these reasons, the amendment to the claims raises new issues under 35 U.S.C. 112, first paragraph that would require further consideration.

2. The request for reconsideration has been considered but does not place the application in condition for allowance for the reasons of record in view of the non-entry of the after-final

amendment of July 10, 2001. Furthermore, in the response filed July 10, 2001, Applicants traverse the previous grounds of rejection by stating that Applicants have shown that gene products expressed in a host tissue but not in other tissues can be used to indicate disease when they are found to be overexpressed in tissues outside of their host tissue. Applicants point to the findings obtained with CEA and PSA as evidence of the fact that expression of a tissue specific gene outside of its "host tissue" is correlated with disease. This argument is not persuasive because Applicants have not shown that expression of all tissue specific gene products outside of their "host tissue" is associated with disease. Thereby, the findings obtained with CEA and PSA cannot be applied to all tissue-specific polynucleotides, and particularly cannot be applied to polynucleotides comprising SEQ ID NO: 1-14. Applicants argue that they have provided evidence that RING finger proteins are associated with cancer and indicate that BS203 is a member of the RING finger family. This argument is not persuasive because Applicants have not provided sufficient evidence to support the contention that any one of SEQ ID NO: 1-14 is a RING finger protein or that all members of the RING finger family are correlated with cancer. As discussed in the previous office action, the fact that the claimed nucleic acids encode for proteins having domains known to be present in RING finger proteins does not indicate that the claimed nucleic acids encode for proteins having the same functional properties as the RING finger proteins described in the prior art. There is also no evidence to support the contention that the differences in the RING finger motif of BS203 compared to the consensus RING finger motif do not affect the activity of the RING finger protein. In addition, identifying domains within a new

protein which are conserved with other known proteins, does not indicate what specific function the new protein might have. Again, Applicants have not provided evidence to support the contention that any one of SEQ ID NO: 1-14 is correlated with the occurrence of a specific type of cancer. Applicant "reminds the Examiner that a protein or nucleic acid marker is useful not only for the direct detection of cancer in a biopsy sample but may also be useful in making a diagnosis or prognosis regarding the patient's disease status". In support of this statement, applicant points to the findings associated with overexpression of HER-2-neu. These arguments have been fully considered but are not persuasive because the findings associated with HER-2-neu are not relevant to the instant invention. The ability to use HER-2-neu expression to diagnose or prognose a patient's disease status is not based solely on the finding that HER-2-neu is expressed in breast cells, but rather on the finding that over-expression of HER-2-neu is associated with the occurrence of breast cancer. That is, the association between HER-2-neu expression and cancer has been fully characterized in the art. However, no association has been established for expression of sequences comprising SEQ ID NO: 1-14 and cancer. For these reasons, it is maintained that differential expression of SEQ ID NO: 1-14 does not indicate that these nucleic acid can be used to diagnose any particular disease.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

July 23, 2001

Carla Myers

CARLA J. MYERS
PRIMARY EXAMINER